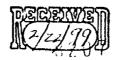
P&Y American Dietary Supplements, Inc.





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Robert J. Moore, Ph.D.
Director, Division of Programs and Enforcement Policy
Office of Special Nutritionals (HFS-455), CFSAN
U.S. Food and Drug Administration
200 "C" Street, S.W.
Washington, D.C. 20204
February 15, 1999

Dear Dr. Moore,

Pursuant to the requirements of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act for Dietary Supplement, P&Y American Dietary Supplements Inc., on its own behalf and on behalf of Hangzhou Zhong-Mei-Hua-Dong Pharmaceutical co., Ltd., Hangzhou, China, wishes to notify the Food and Drug Administration that we will market a dietary supplement, CORBRINTM Capsule, on the US market with the following structure-function claims:

"The CORBRINTM capsule contains 200 mg standardized highly purified liquid extract powder of the cultured Mycelia of *Cordycep sinensis*. It is a natural tonic for enhancement of energy, physical performance and endurance, and for overcoming chronic fatigue of the body. It also improves antioxidant activity, strengthen immune functions of lung and kidney." This statement has not been evaluated by the Food and Drug Administration. It is not intended to diagnose, treat, cure or prevent any disease."

I certify that the information present here is accurate and has substantiation that it is truthful and not misleading. A list of published reference articles and a copy of label information are attached for your reference.

2-16-49

Sincerely yours,

Simon Ko President

Attachments

LET 3/8/

References

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- 3. Ji H, Li Z, Po ZM, Chen F and Chen PS: Effects of cultural Mycelium of *Cordyceps sinensis* on gentamycin-induced acute kidney injury in the rat. *Journal of China Pharm.*, 27:245-249 (1996).
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CORBRIN CAPSULE A DIETARY SUPPLEMENT

60 Capsules

"The CORBRINTM capsule contains 200 mg standardized highly purified liquid extract powder of the cultured Mycelia of *Cordycep sinensis*. It is a natural tonic for enhancement of energy, physical performance and endurance, and for overcoming chronic fatigue of the body. It improves antioxidant activity, strengthen immune functions of lung and kidney." This statement has not been evaluated by the Food and Drug Administration. It is not intended to diagnose, treat, cure or prevent any disease.

DIRECTIONS FOR USE: Take 5 capsules 3 times per day.

Supplement Facts

Serving Size 5 caplets

Total Serving: 12 servings per box

Amount per Serving (5 caplets):

Mycelia of Cordyceps sinensis

* Daily Value not established.

Contains no artificial colors or preservatives. Please keep in cool, dry area.

Manufactured by:

Hangzhou Zhong-Mei-Hua-Dong Pharmaceutical co., Ltd. Hangzhou, China.

1 g*

Distributed by:

P&Y American Dietary Supplements, INC., Marathon, Wisconsin, U.S.A.